PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GBI0004P	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/07307	International filing date *(day/month/year)* 10 APRIL 1998	Priority date *(day/month/year)* 18 APRIL 1997
International Patent Classification (IPC) or national classification and IPC IPC(7): A01N 63/00 and US Cl.: 424/93.46		
Applicant GANEDEN BIOTECH, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 NOVEMBER 1998	05 SEPTEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VERA AFREMOVA Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/07307

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-37, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the claims:
pages 38-42, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-9, 14-24 and 44 .

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/07307

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	6-8, 15, 16 and 18-24	YES
	Claims	1-5, 9, 14, 17 and 44	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-9, 14-24 and 44	NO
Industrial Applicability (IA)	Claims	1-9, 14-24 and 44	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-5 and 44 lack novelty under PCT Article 33(2) as being anticipated by WO 93/14187.

The claims are directed to composition comprising dried cells or spores of bacteria belonging to the genus Bacillus and pharmaceutically acceptable carrier suitable for skin or membrane of a mammal. Some claims are further drawn to particular bacterial species such as Bacillus coagulans and to particular amounts of cells such as 10x3 to 10x12 viable cells per gram of the composition.

The cited reference anticipates the claimed invention because it discloses an identical composition as claimed which comprises lyophilized (dried) cells and spores of Bacillus coagulans in amount 50-100 billions cells per gram of the composition (page 3, lines 9, 31 and 34). The cited composition comprises physiological solution or pharmaceutically acceptable carrier (page 3, line 31).

Claims 1, 3 and 9 lack novelty under PCT Article 33(2) as being anticipated by JP 63-96107.

The claims are directed to composition comprising dried cells of bacteria of the genus Bacillus and pharmaceutically acceptable carrier suitable for skin of a mammal. Some claims are further drawn to particular form of the composition such as powder.

The cited patent teaches a powdered cosmetic composition with freeze-dried cells of Bacillus for topical facial application (abstract). The cited patent further discloses topical application of the composition comprising live microorganisms to human body, facial skin, hair (abstract).

Claims 1, 5, 14, 17 and 44 lack novelty under PCT Article 33(2) as being anticipated by Siegel et al.

The claims are directed to a composition comprising dried cells of bacteria belonging to the genus Bacillus and pharmaceutically acceptable carrier suitable for skin or membrane of a mammal. Some claims are directed to a method comprising steps of applying topically the claimed composition and allowing Bacillus cells to growth for sufficient time in order to inhibit

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
growth of other microorganisms. Some claims are further drawn to particular amounts of cells such as 10x3 to 10x12 viable cells per gram of the composition.

The cited reference teaches a topical composition comprising 4.48x10x6 CFU of Bacillus sphaericus and a method comprising steps of applying the disclosed composition to rabbit conjunctival membrane and allowing bacterial cells to growth for 6-8 weeks to inhibit Bacillus thuringiensis infection.

Claims 1-9, 14-24 and 44 lack an inventive step under PCT Article 33(3) as being obvious over WO 93/14187 or JP 63-96107 or Siegel et al. taken with Schoeni et al.

The claims are directed to a composition comprising dried cells or spores of bacteria belonging to the genus Bacillus and pharmaceutically acceptable carrier suitable for skin or membrane of a mammal. Some claims are directed to a method comprising steps of topically applying the claimed composition and allowing Bacillus cells to growth for sufficient time in order to inhibit growth of other microorganisms. Some claims are further drawn to particular bacterial species, to particular amounts of cells such as 10x3 to 10x12 viable cells per gram of the composition and to incorporation of fructo-oligosaccharide (FSO) into composition with bacterial cells.

The cited references WO 93/14187 or JP 63-96107 or Siegel et al. are relied upon as explained above for the disclosure of compositions with live bacterial cells and methods of topical application to mammalian skin or membrane of the composition with live bacterial cells or probiotics. The references are lacking the particular disclosure of incorporation of FSO into composition with bacterial cells. However, Schoeni et al. teach the benefits of FSO incorporation into probiotic compositions for elimination and/or prevention of growth of pathogenic microorganisms by competitive exclusion. And, therefore, the claimed invention is considered to be obvious over the cited references combined since composition with probiotic or viable bacterial cells are known in the method for topical application and incorporation of FSO into probiotic compositions has been suggested in the prior art for enhancing effects of elimination of pathogenic infection by beneficial probiotic bacteria.

---------- NEW CITATIONS ----------

NONE